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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/613,092	07/10/2000	Edwin W. Ades	68430	9419

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NEEDLE & ROSENBERG P C
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ATLANTA, GA 30303-1811

EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 04/30/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/613,092

Applicant(s)
Ades et al.

Examiner
S. Devi, Ph.D.

Art Unit
1645



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 24, 2003
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above, claim(s) 2-10 and 12-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☒ Claim(s) 11 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 14. 6) ☐ Other: _____

RESPONSE TO APPLICANTS' AMENDMENT

Applicants' Amendment

- 1) Acknowledgment is made of Applicants' amendment filed 02/24/03 (paper no. 16) in response to the non-final office Action mailed 09/17/02 (paper no. 13). With this, Applicants have amended the specification.

The Office appreciates Applicants' courtesy in supplying a copy of the pending claims from the co-pending application, SN 09/754,809.

Status of Claims

- 2) Claims 1 and 11 have been amended via the amendment filed 02/24/03.
Claims 1-20 are pending.
Claims 1 and 11 are under examination.

Information Disclosure Statement

- 3) Acknowledgment is made of Applicants' information disclosure statement filed 09/03/02 (paper no. 14). The information referred to therein has been considered and a signed copy of the same is attached to this Office Action (paper no. 17).

Prior Citation of Title 35 Sections

- 4) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

- 5) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Objection(s) Withdrawn

- 6) The objection to the specification made in paragraph 8(a) of the Office Action mailed 09/17/02 (paper no. 13) is withdrawn in light of Applicants' amendment to the specification.

Objection(s) Maintained

- 7) The objection to the specification made in paragraph 8(b) of the Office Action mailed 09/17/02 (paper no. 13) with regard to sequence non-compliance is maintained for reasons set forth

therein.

With Applicants state that they have submitted a Sequence Listing as required under 37 C.F.R 1.821 to overcome the objection. However, neither a Sequence Listing is submitted along with the amendment filed 02/24/03, nor has the specification on page 28, line 27 and page 29 line 9 been amended identifying sequences 'CYGG' and "LXCC" with a SEQ ID number. The objection stands.

Rejection(s) Withdrawn

- 8) The rejection of claim 1 made in paragraph 10 of the Office Action mailed 09/17/02 (paper no. 13) under 35 U.S.C § 101 as being directed to a non-statutory subject matter, is withdrawn in light of Applicants' amendment to the claim.
- 9) The rejection of claim 1 made in paragraph 11(a) of the Office Action mailed 09/17/02 (paper no. 13) under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.
- 10) The rejection of claim 11 made in paragraph 11(b) of the Office Action mailed 09/17/02 (paper no. 13) under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.
- 11) The rejection of claim 11 made in paragraph 11(c) of the Office Action mailed 09/17/02 (paper no. 13) under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn upon further consideration.
- 12) The rejection of claim 1 made in paragraph 13 of the Office Action mailed 10/23/01 (paper no. 17) under 35 U.S.C § 102(b) as being anticipated by De *et al.* (*Pathobiology* 67: 115-122, May-June 1999), is withdrawn. Applicants are asked to note the new/modified rejection made below.
- 13) The rejection of claims 1 and 11 made in paragraph 14 of the Office Action mailed 09/17/02 (paper no. 13) under 35 U.S.C § 102(b) as being anticipated by Ades *et al.* (WO 99/45121 - Applicants' IDS) ('121), is withdrawn. Applicants are asked to note the new/modified rejection made below.

Rejection(s) under 35 U.S.C. § 103

- 14) The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness

rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 148 USPQ 459, that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or unobviousness.

15) Claim 1 is rejected under 35 U.S.C § 103(a) as being unpatentable over Ades *et al.* (WO 99/45121 - Applicants' IDS) ('121) in view of Tam (*In: Peptide Antigens: A Practical Approach*. (Ed) Wisdom G.B. IRL Press, Oxford University Press, New York, 1993, pp. 83-90), or Huang *et al.* (*Mol. Immunol.* 31: 1191-1199, 1994).

It is noted that the prior art patent '121 lists Tharpe JA, Westerink MAJ and Zeiler JL as co-inventors and therefore qualifies as prior art by 'another' under 35 U.S.C § 102. It is further noted that the peptide of claim 1 is structurally undefined or unidentified by a SEQ ID number.

Ades *et al.* ('121) disclosed a peptide that immunospecifically binds to a monoclonal antibody obtained in response to immunizing an animal with *Streptococcus pneumoniae* PsaA. The peptide comprises the amino acid sequences of SEQ ID N: 5, 6 o 7 (see claims 12-15 and 20; and page 19). A sequence search performed at the Office showed that Aedes' peptides show 100% sequence identity with the instantly claimed SEQ ID NO: 5, 6 and 7. See the sequence search reports attached to the Office Action mailed 09/17/02 (paper no. 13). Ades *et al.* ('121) disclosed the peptide conjugated to a carrier protein or an immunomodulatory adjuvant (see page 21).

Ades *et al.* ('121) differ from the instant invention in not expressly disclosing that the PsaA peptide is present as a multiple antigenic peptide.

However, it was routine and conventional in the art at the time of the invention to modify a peptide as a multiple antigen peptide with a built-in-adjuvant for the purpose of providing a very high

density of the peptide epitope. For instance, see the teachings of Tam on pages 87, 83 and 84.

Huang *et al.* taught the disadvantage of presenting a peptide as a peptide-protein carrier or as an adjuvant mixture, the disadvantage being the difficulty in defining the chemical composition and stoichiometry of such a mixture. Huang *et al.* taught the advantages of presenting a peptide via a MAP system. Huang *et al.* taught that the MAP system permits the amplification of antigens 4 to 8-fold to attain a macromolecule and avoids the use of a protein carrier as well as attendant structural ambiguity. See page 1191.

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify Ades's PsaA peptide as a multiple antigen peptide with a built-in-adjuvant as taught by Tam, to produce the instant invention, with a reasonable expectation of success. One of skill in the art would have been motivated to produce the instant invention for the expected benefit of presenting Ades's PsaA peptide as a multiple antigen peptide with a built-in-adjuvant for the purpose of advantageously providing a very high density of the peptide mimic as taught by Tam, or for avoiding the use of a protein carrier and avoiding structural ambiguity of a conjugate as taught by Huang *et al.*

Claim 1 is *prima facie* obvious over the prior art of record.

Remarks

16) Claim 1 stands rejected. Claim 11 stands objected for being dependent from a rejected claim.

17) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center's telephone number is (703) 308-4242, which is able to receive transmissions 24 hours a day and 7 days a week. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

18) Any inquiry concerning this communication or earlier communication(s) from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A message may be left on the Examiner's voice mail service. The Examiner can normally be reached on Monday to Friday from 7.15 a.m to 4.15 p.m. except one day each bi-week which would be disclosed on the

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Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

April, 2003


S. DEVI, PH.D.
PRIMARY EXAMINER